IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	)	
THIS DOCUMENT RELATES TO:	)	C.A. No. 05-360 (KAJ)
C.A. Nos. 05-360, 05-365, 05-390, 05-394, 05-426, 05-450, 05-467, 05-482, 05-475, 05-516, 05-695	)	REDACTED

DEFENDANTS' ANSWERING BRIEF IN OPPOSITION TO BRIEF IN SUPPORT OF INDIRECT PURCHASER PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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Dated: August 16, 2006
Redacted Filing Date: May 13, 2008

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PRELIMINARY STATEMENT

The opening brief of the putative class representatives for a disparate group of "indirect purchasers" largely ignores the fundamental flaws of their proposed class. The end result of what they propose is a litigation that is completely unmanageable, unfair both to unnamed class members and defendants, and incapable of satisfying plaintiffs' burden under Rule 23.

The problems start with plaintiffs' attempt to define a class requiring the application of consumer protection, common law fraud and the unjust enrichment laws from all 50 states and the District of Columbia. Differences in these laws, and the legislative and judicial precedent that define them, have led numerous courts to reject class certification. Plaintiffs fail to explain how this Court could fairly and adequately instruct a jury hearing plaintiffs' claims under so many different laws. The lack of commonality and the manageability issues raised by plaintiffs' sweeping class preclude class certification.

Plaintiffs' desire to represent a class of indirect purchasers based on state antitrust statutes from 23 different states should fare no better. Invoking an "overcharge" theory and suggesting the use of "average" prices, plaintiffs attempt to gloss over the fact that their approach is unworkable. Numerous courts have refused to certify classes of indirect purchasers where, as here, the economic methodology is insufficient to accurately determine injury and damages. The putative class is composed of a broad array of indirect purchasers, including individual consumers and institutional health plans. They pay different prices for TriCor based on complex contractual relationships with retailers, wholesalers, pharmacy benefit managers and even other members of their own class.

More fundamentally, an overcharge theory simply does not fit the facts of this case—as alleged by plaintiffs. An overcharge theory should compare the price paid for a product (branded TriCor) in the actual world with the price that would have been paid for the same product (branded

TriCor) in the "but for" world. But here, the vast majority of plaintiffs would not have bought branded TriCor in the "but for" world. If, as plaintiffs assume, defendants had not introduced new TriCor formulations and defendants' TriCor 200 mg capsules had faced generic fenofibrate competition in Spring 2002, defendants would have stopped promoting TriCor. REDACTED

Instead, total fenofibrate prescriptions would have shrunk.

In plaintiffs' "but for" world, the vast majority of the plaintiffs would have purchased either a different dyslipidemia drug (*e.g.*, one of the statins that dominate the dyslipidemia market) in the place of branded TriCor or they would have purchased an AB-rated 200 mg capsule. Neither of these "but for" world purchases means a plaintiff was "overcharged" for branded TriCor in the actual world.

Plaintiffs also disregard the complexity of the contractual relationships that contribute to the "price" each of them paid for TriCor or Teva's competing branded generic. Health plans negotiate contracts with retail drug stores and with pharmacy benefit managers involving reimbursement for prescription drugs; the terms of which will be driven by the relative economic power of the contracting parties – none of which will have anything to do with TriCor. The same holds true for individual consumers. The "price" they pay for Tricor is highly dependent on the terms of their coverage which can vary (even from year to year) from flat co-pays, percentage co-pays and tiered co-pays. Similarly, individual health plans, directly and indirectly, secure rebates on TriCor dependent on a variety of factors.

Accordingly, determining the "price" a particular plaintiff paid for TriCor requires an individualized look at that plaintiffs' contractual relationships.

Plaintiffs similarly ignore the need for individualized scrutiny into the ability of many of

them to drive the utilization of Teva's 200 mg capsule to determine whether they have been injured or damaged. Institutional class members regularly use their formulary management to shift patients to alternative formulations of products and even different drugs (chemical entities). REDACTED

Plaintiffs' last refuge, a proposed class for unspecified injunctive relief, is an inferior mechanism for pursuing such relief. Other plaintiffs are seeking injunctive relief against defendants. Plaintiffs fail to demonstrate why the Court and the litigants need a costly and time-consuming class action mechanism in order to obtain any appropriate injunctive relief.

Accordingly, as discussed further below, plaintiffs' class certification motion should be denied. At a minimum, the Court should permit defendants' discovery of unnamed class representatives, which the Court denied without prejudice, to further demonstrate the predominance of individual issues.

STATEMENT OF FACTS[1]

A. The Dyslipidemia Market

Dyslipidemia is a disorder of lipid levels within a patient that can contribute to cardiovascular disease – the nation's leading cause of death. Lipids include LDL ("bad cholesterol"), and HDL ("good cholesterol"), and triglycerides (fatty acids). A dyslipidemic patient might have high LDL, low HDL, and/or high triglycerides. A physician has a plethora of drug options to chose from when treating dyslipidemia, including statins (which dominate the dyslipidemia market with over 80% of total prescriptions), fibrates (~8.5%), niacins (~2.5%) and other drugs (~9%).

Fibrates have been used for many years to treat a range of metabolic disorders, including high cholesterol (often referred to as "dyslipidemia"). REDACTED

However, like many fibrates, fenofibrate has one significant drawback: it is very insoluble in the gastric system. As a result, the drug's natural "bioavailability" is low, inhibiting its therapeutic effect. *Id.* at ¶4.

Fournier, later joined by Abbott, has continually worked to develop methods of making and delivering fenofibrate products with greater bioavailability. *Id.* at ¶¶6, 10. The first Fournier fenofibrate product was approved by the FDA in 1993, but it had limited bioavailability and was not marketed here in the United States. In 1997, Fournier sought FDA approval for a new fenofibrate formulation with greater bioavailability, the TriCor 67 mg capsule. The 67 mg product had to be

[1] While an inquiry into the likelihood of the plaintiffs' success on the merits is not relevant to the issue of whether certification is proper, *Eisen v. Carlisle & Jacquelin,* 417 U.S. 156, 177-78 (1974), an inquiry into facts relevant to class certification is required. *See, e.g., Thorn v. Jefferson-Pilot Life Ins. Co.,* 445 F.3d 311, 319 (4th Cir. 2006) ("At the class certification phase, the district court must take a 'close look' at the facts relevant to the certification question and, if necessary, make specific findings on the propriety of certification."); *General Telephone Co. of Southwest v. Falcon,* 457 U.S. 147, 160 (1982) ("[S]ometimes it may be necessary for the district court to probe behind the pleadings before coming to rest on the certification question.").

taken three times a day to achieve a full therapeutic dose. *Id.* at ¶5. REDACTED

The FDA approved the 67 mg formulation in February 1998 and Abbott began thereafter to detail TriCor to physicians who treat patients with cholesterol issues. In February 1999, Abbott filed a supplemental NDA seeking FDA approval for a 200 mg daily capsule which would allow a patient to take one capsule a day instead of three. *Id.*

As noted above, TriCor competes in the highly competitive dyslipidemia market, which was then and is today dominated by the "statin" drugs (such as Zocor, Crestor and Lipitor, each of which have many billions of dollars in annual sales). REDACTED

B. Introduction of a New TriCor Formulation

Well before entering into its license agreement with Abbott, Fournier had been working on improving TriCor. REDACTED

Id. at ¶6. This work led to a regulatory application in the U.S. and elsewhere for a lower dosage TriCor product that produced the same amount of active ingredient in the bloodstream as the 200 mg capsule. *Id.* at ¶7. In November 1999, Abbott applied for approval for, and in September 2001, the FDA approved, a 160 mg and 54 mg TriCor product (the "tablet product").[2] *Id.* at ¶¶7-8.

As a result of this new technology, Abbott could market a new tablet product with better bioavailability. This new tablet also had an expanded FDA label, showing that it was indicated to

[2] Abbott's application for approval for the 160 mg tablet was filed a month prior to the first generic filing for approval of a 200 mg capsule, Teva's in December 1999.

raise HDL, along with the existing indication to treat triglycerides and lower LDL. *Id.* at ¶7. Like the old formulation, the 160 mg TriCor labeling required the product to be taken with a meal. *Id.* at ¶10.

REDACTED

C. A Generic Fenofibrate is Introduced

In December 1999 and May 2000, Novopharm/Teva[4] and Impax, respectively, filed ANDAs for a generic 200 mg fenofibrate capsule. Abbott and Fournier filed patent infringement lawsuits against both Teva and Impax which initiated the 30-month stay provisions of Hatch-Waxman.

The Indirect Purchasers do not allege that the pendency of the "capsule" patent litigation delayed the entry of a generic 200 mg fenofibrate. Nor could they. Impax did not receive tentative approval until February 2002 and then it was barred by Teva's statutory first-filer 180 day period of exclusivity.

REDACTED

[3] REDACTED

See Ex. 3 (Jones Decl.) at ¶9.

[4] Teva acquired Novopharm in 2000. For the purposes of this brief, "Teva" will be used to refer both to Teva and to Novopharm.

REDACTED

TriCor 047751; TriCor 029117-029119).

REDACTED

REDACTED

Had the world evolved as plaintiffs envision, fenofibrate prescriptions would have peaked in 2001-02 and begun to fall as the heavily promoted, dominant statins took away share from fenofibrate. But with the introduction of the new TriCor formulations and continued support by Abbott and Fournier, TriCor's (and total fenofibrate) prescriptions continued to increase. REDACTED

D. Introduction of a TriCor 145 mg tablet.

As noted earlier, one of the continuing drawbacks of TriCor was that it needed to be taken with food. REDACTED

REDACTED

In 2003, Abbott filed a supplemental NDA seeking approval for a 145 mg tablet TriCor product. The application was granted in November 2004. In December 2004, Abbott introduced a new formulation ("NFE product") that (i) had a lower dose of fenofibrate (145 mg) and (ii) as indicated by its FDA-approved label, did not need to be taken with food. *Id.* at ¶¶11-13. Because the new product had the same bioavailability as the old tablet, but with the administrative benefit of a "no food effect," there was no reason for Abbott and Fournier to continue selling the old formulation.

Physicians readily adopted the new formulation, although they had a choice among TriCor 145 mg and 160 mg, and Teva's 200 mg product. Plaintiffs allege that physicians were "forced" to prescribe the new TriCor formulation because the old TriCor 160 mg formulation was discontinued. The truth is that both the 160 mg and 145 mg were available for some time. *Many months after* the new 145 mg TriCor was introduced, Abbott agreed to take back unused inventory of the old formulation. *Id.* at ¶14. Moreover, physicians continued to have a choice among fenofibrates for their patients—they could prescribe TriCor's 145 mg, Teva's 200 mg product, any of the new fenofibrate products coming to the market or alternatively any other cholesterol-lowering agent. (*See* below).

In Summer 2002, Teva filed an ANDA directed at the TriCor 160 mg formulation that was introduced in 2001. Impax followed within months. In October 2002, defendants filed an action in this Court alleging infringement of their '405 patent against Teva, and against Impax in January 2003. In November 2003, the '881 patent issued, and was similarly the subject of challenge

and litigation. The FDA granted tentative approval to Teva's 160 mg and 54 mg tablet formulations on March 5, 2004. The statutory 30-month Hatch-Waxman stay related to the '405 patent expired on February 21, 2005.

On May 6, 2005, this Court ruled on the motions for summary judgment, granting them in part and denying them in part, and setting for trial claim 6 of the '405 patent, and claims 5, 10, 19, 26, 31, and 41 of the '881 patent. *Abbott Laboratories v. Impax Laboratories, Inc.*, No. 03-120-KAJ (consolidated) (D. Del. May 6, 2005 Mem. Op.). Following the decisions on summary judgment, the parties settled the patent infringement claims.

The FDA issued final approval of Teva's tablet ANDA on May 13, 2005 and Teva was eligible to begin marketing a tablet on that date. REDACTED

Impax should have become eligible to market a 160 mg fenofibrate tablet upon expiration of Teva's Hatch-Waxman exclusivity period in November 2005, but to date, has not received final approval from the FDA to market a 160 mg fenofibrate tablet product. Impax has been eligible to sell a 200 mg fenofibrate capsule since October 2003, but has never done so. *Id.* at ¶17.

Other manufacturers have introduced fenofibrate products that compete against TriCor. Reliant (Antara) and First Horizon (Triglide) market fenofibrate products in the U.S. *Id.* at ¶18-19. Canada-based Cipher (Lipofen) has approval to market its fenofibrate product in the U.S., but has not launched its product. *Id.* at ¶20. Both Antara and Triglide are currently marketed as "no food effect" products. Reliant markets its 130 mg Antara product as the lowest effective dose available.

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[5] REDACTED

Id. at ¶18.

E. Plaintiffs' Proposed "Indirect Purchaser" class

Plaintiffs have defined a class of indirect purchasers comprising a variety of so-called "end-payers" as:

> All persons or entities in the United States and its territories who purchased, paid and/or reimbursed for fenofibrate products … intended for consumption by themselves, their families, or their members, employees or insureds … during the period from April 9, 2002 … Excluded from the class are all defendants … all governmental entities, and all persons or entities that purchased fenofibrate products: (i) for purposes of resale, or (ii) directly from any of the defendants.

This putative class includes a variety of entities and individuals: a) cash-paying customers; b) patients who have prescription drug insurance, but who pay part of the cost (e.g., via co-pays); c) insurance companies that pay that part of the cost not paid by insureds, but that do not themselves dispense drugs; d) employers who pay/reimburse for drugs used by their employees; e) groups such as union benefit plans that pay/reimburse for drugs used by their members; and e) indirect-purchasing managed care entities (***e.g.***, staff-model HMOs) that have insureds but do not resell drugs. *See* Ex. 1 (Sherry Report) at ¶17, 48.

1. The proposed class is diverse and includes differently-situated members.

The physical distribution system for drugs and the methods of payment and reimbursement are complex and multi-leveled.[6] REDACTED

[6] REDACTED

REDACTED

- A patient without a health insurance plan that provides prescription drug coverage will pay the price set by the retailer. Pricing on the same drug to so-called "cash customers" can vary widely from pharmacy to pharmacy even within the same geographic area.[7]
- Patients with prescription drug coverage typically pay only part of the cost of their prescriptions in the form of a co-payment or a deductible. The amount of co-payments and deductibles applicable to any given patient differ greatly over different plans. *See* Ex. 2 (Navarro Report) at ¶¶78-84. For example, many health plans create incentives for patients to use certain "preferred" drugs by requiring high co-pays for non-preferred drugs.

As noted above, in addition to individuals who are prescribed TriCor, plaintiffs' putative class is composed of a variety of entities that provide reimbursement for prescription drugs. These entities range from small union benefit health plans to large corporate insurance companies to HMOs and self-insured companies. What these institutional end payers ultimately pay for a prescription drug is function of a number of factors. For example:

- Some end payers will enter into contracts with pharmaceutical manufacturers in which they receive discounts and rebates from the manufacturer in exchange for inclusion on the end payers' drug formulary. *Id.* at ¶¶55, 93-95.
- Self-insured companies and health and welfare trusts *sometimes* have the power to obtain discounts. Pharmacy benefit managers (PBMs)[8] representing certain of these class members can negotiate rebates from drug manufacturers *if* a) the class member has a large number of employees (or members) *and* b) the class member uses a formulary. The discount will vary from one class member to another. *Id.* at ¶¶33-44.

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[7] A recent study in New York found that retail prices for drugs in retail pharmacies in New York City varied by as much as 100% for the same prescription. A 2004 study by the New York City Council found vast differences in the prices charged at retail within a single neighborhood. See "Prescription Drug Prices: All Over the Map" Staff Report to the Committee on Oversight and Investigations, February 2004, at 2 (attached hereto as Exhibit 6). In just the borough of Manhattan, the study found cash prices for Prevacid varied by as much as $78.05 per prescription. For the arthritis drug Celebrex, the study found that pharmacy prices in New York City varied from $60.16 to $128.00 for the same quantity and strength – a difference of over 100%. *Id.* at 14.

[8] REDACTED

- For TriCor dispensed through retail drug stores, entity end payers have contracts with retailers in which the store agrees to be within the plan's "network" of pharmacy providers in exchange for a negotiated payment schedule. The total reimbursement to the retailer will vary from health plan to health plan based on the respective economic bargaining power of the retail drug store (*e.g.*, an independent vs. a national chain) and the end payer, and the formula utilized will determine the cost of a specific drug. *Id.* at ¶¶ 64-70.
- REDACTED

- REDACTED

Thus, the "price" paid for TriCor will be dependent on these multiple levels of contractual negotiations – involving factors both related and unrelated to TriCor.

2. Certain end-payers can influence which drug is prescribed.

Whether a patient receives TriCor and the price of TriCor in a particular transaction can be greatly influenced by a health plan or one of its agents. In an effort to control prescription drug costs, many entity end payers exercise control over the prescribing/dispensing behavior of physicians through formulary enforcement. REDACTED

In many cases, these entities use these methods to encourage physicians and pharmacists to engage in what is known as "therapeutic substitution" – that is, prescribing or dispensing a

different molecule to treat the same condition.[9] REDACTED

Since April 2002, when Teva introduced its 200 mg fenofibrate product, a number of entity end payers (directly or through a PBM) have had the ability to influence whether physicians prescribe and retailers dispense TriCor or Teva's 200 mg fenofibrate product to their members. *See* Ex.2 (Navarro Report) at ¶¶56-57. REDACTED

Most plans did not do so, but that does not mean they lacked the capacity to do so. Determining why they did not requires an individualized inquiry into the structure of end payers (or its PBM's) health plan and decision making.

ARGUMENT

I. PLAINTIFFS BEAR THE BURDEN OF SHOWING THAT THE PROPOSED CLASS SATISFIES EACH OF THE REQUIREMENTS OF THE FEDERAL RULES OF CIVIL PROCEDURE.

Plaintiffs bear the burden of proving that the proposed class meets each and every one of

[9] For example, a formulary might include only three of six available angiotensin II receptor blocker drugs ("ARB drugs") – which are different molecules. Physicians would not prescribe an omitted ARB drug for their patients covered by that formulary. If the physician did prescribe an omitted ARB drug, the patient's pharmacist would call the physician to obtain authorization to switch the prescription to the formulary ARB drug. Similarly, if one ARB drug were on Tier II and another on Tier III, the physician and pharmacist would be influenced to utilize the Tier II ARB drug.

the prerequisites for class certification. *See Davis v. Romney*, 490 F.2d 1360, 1366 (3d Cir. 1974). Moreover, plaintiffs must demonstrate that the class mechanism is a superior method for the adjudication of their claims and that the case is "manageable" as a class action, in light of all possible variations in fact, laws, and proof. In reviewing plaintiffs' arguments, this Court must apply a "rigorous" analysis. *See In re Currency Conversion Fee Antitrust Litig*., 230 F.R.D. 303, 306 (S.D.N.Y. 2004), *citing Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 161 (1982).

Plaintiffs' motion is notable for the extent to which it relies on language from class action *settlement cases.* The precedential value of these authorities is limited. The Supreme Court and the Third Circuit have noted expressly that the certification of a settlement class does not require the court to consider the "manageability" of the class. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 619-620 (1997) ("[c]onfronted with a request for settlement-only class certification, a district court need not inquire whether the case, if tried, would present intractable management problems, *see* Fed. Rule Civ. Proc. 23(b)(3)(D), for the proposal is that there be no trial").

In *In re Warfarin Sodium Antitrust Litig*., 391 F.3d 516, 529 (3d Cir. 2004), a case relied on heavily by plaintiffs, the Third Circuit noted that certification of a class for settlement purposes is subject to a less rigorous analysis than a class sought to be certified for trial:

> *Bridgestone* is distinguishable from the instant matter because that case concerned certification of a class for purposes of litigation, not a class solely for purposes of settlement, which is at issue in this case. **The difference is key**. In certification of litigation classes for claims arising under the laws of the fifty states, we have previously noted that the district court must determine whether variations in state laws present the types of insuperable obstacles which render class action litigation unmanageable... [W]hen dealing with variations in state laws, the same concerns with regards to case manageability that arise with litigation classes ***are not present with settlement classes, and thus those variations are irrelevant to certification of a settlement class.***

Id. at 529 (emphasis added); *see also In re LifeUSA Holding, Inc*., 242 F.3d 136, 146 n.10 (3d Cir. 2001) ("A settlement class, as distinct from a class action to be tried, does not implicate trial

management problems.") (internal citation omitted). The Third Circuit further noted that *if* the *Warfarin* class were to proceed to trial, the difficulties caused by differences in state law claims were "significant[ly]" likely to cause the court to decertify the class. *Warfarin*, 391 F.3d at 537. As described below, these same problems are present here.

II. THE PROPOSED CLASS BASED ON STATE CONSUMER PROTECTION STATUTES AND COMMON LAW FRAUD DOES NOT SATISFY RULE 23

Counts II, III and IV and V of the Amended Complaint allege or implicate violations of the consumer protection and consumer fraud laws of all fifty states and the District of Columbia. Amend. Compl. at ¶¶ 111-125. If this putative class is certified, the Court will be obligated by constitutional due process requirements to apply the consumer protection and consumer fraud statutes of fifty-one different jurisdictions. *See, e.g., In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332, 348-49 (D.N.J. 1997) ("Each Plaintiff's home state has an interest in protecting its consumers…and in delineating the scope of recovery for its own citizens under its own laws."); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 277 (D. Mass. 2004) (noting that failing to apply to each challenged transaction the law of the state in which the transaction occurred would be "at best a 'novelty,' and at worst a violation of constitutional limitations").[10]

Courts have been very skeptical of efforts to certify such classes, finding either a lack of "commonality" or insurmountable management issues. *Haley v. Medtronic, Inc.*, 169 F.R.D. 643, 649 (C.D.Cal., 1996) ("[C]ommonality may be found lacking where a common fact issue would be resolved differently under different state laws applicable to the facts of the case.") (citing *In re Northern Dist. of Calif. Dalkon Shield Litig*., 693 F2d 847, 850 (9th Cir. 1982)(citing different punitive damages standards under the laws of different states); *Kaczmarek v. IBM Corp.* 186 F.R.D.

[10] While the Relafen court certified a class, it did so only for states with similar laws, excluding plaintiffs from states with laws that conflicted. Id. at 278-87.

307, 312-313 (S.D.N.Y. 1999) ("The prospect of determining the law of all fifty states and then applying the materially different laws that exist for some of the claims in this case would make this class action too complicated and unmanageable").[11] In addition, courts have held that class treatment of consumer fraud cases is not "superior" to individual adjudication. *In re LifeUSA Holding, Inc.*, 242 F.3d 136, 148 (PA 2001) (holding that despite the modest size of individual claims, class treatment in the consumer fraud context was not "superior" because "the individual adjudications of causation, reliance… multiple defenses, and application of differing state laws" a class action would be a "thoroughly unwieldy endeavor").

Plaintiffs gloss over the differences in state laws, simply alleging that the statutes are sufficiently uniform to satisfy the predominance requirement. But many courts, including the Supreme Court, have noted that the consumer fraud statutes of the various states are *not* uniform. *See BMW of North America, Inc., v. Gore*, 517 U.S. 559, 568-69 (1996) ("No one doubts that a State may protect its citizens by prohibiting deceptive trade practices ... But the States need not, and *in fact do not, provide such protection in a uniform manner*."); *see also* John S. Kiernan, Michael Potenza, Peter Johnson, *Developments in Consumer Fraud Class Action Law*, 537 PLI/PAT 237, 277 (1998) (noting that actionable conduct under the various consumer fraud acts varies considerably).

Attached as Appendix A to defendants' brief is a chart detailing differences among state consumer protection and state laws. It is those differences that have led courts consistently to recognize that conflicts among state consumer fraud/ consumer protection laws are insurmountable

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[11] *See also Mace v. Van Ru Credit Corp.*, 109 F.3d 338, 341 (7th Cir. 1997) ("[T]he class requirements found in the Federal Rules of Civil Procedure encourage rather specific and limited classes. The typicality and commonality requirements of the Federal Rules ensure that only those plaintiffs or defendants who can advance the *same factual and legal arguments* may be grouped together as a class.") (emphasis added).

obstacles to class certification. *See Montgomery v. New Piper Aircraft, Inc.*, 209 F.R.D. 221, 229 (S.D. Fla. 2002) ("[W]hen a survey of the various deceptive trade practices laws is done, it becomes clear that a class action trial in this case would be wholly unmanageable."); *Clay v. American Tobacco Co.*, 188 F.R.D. 483, 503 (S.D. Ill. 1999) ("the consumer fraud statutes are not proper claims for class certification in this instance'"); *Zapka v. Coca-Cola Co*., No. 99 CV 8238 , 2000 WL 1644539, at *4 (N.D. Ill. Oct. 27, 2000) ("[t]he differences in the required proofs of the states' [consumer fraud] statutes demonstrate that a nationwide certification would not be manageable").[12]

Moreover, the contention that there is a "common" nucleus of facts is not sufficient where, as here, individual issues created by the application of different state laws predominate over the common issues. *See Coca-Cola Bottling Co. v. Coca Cola Co.*, 95 F.R.D. 168, 178 (D. Del. 1983) ("The Court recognizes that there is a certain nucleus of facts… which might be common to the class, but believes that these facts would be submerged by the facts surrounding… the application of different states' laws to each set of facts.").

A. Substantial Variations in State Consumer Protection and Fraud Laws Mean that Individual Issues Predominate over Common Issues.

The variations in state laws described below present an insurmountable obstacle to class certification.

1. Reliance and causation.

Plaintiffs in some states need to demonstrate reliance in order to prevail on their

[12] *See also, e.g., Ruffu v. Johnson & Johnson, Inc*., 181 F.R.D. 341, 344 (E.D. Tex. 1998) (denying class certification in consumer fraud action because of predominance of individual fact questions of whether consumers relied on defendants' alleged misrepresentations); *Freedman v. Arista Records, Inc*., 137 F.R.D. 225, 229 (E.D. Pa. 1991) (denying class certification because individual questions of reliance predominated in action alleging that misrepresentations caused consumers to purchase music albums); *Rosenstein v. CPC Int'l, Inc*., Civ. A. No. 90-4970, 1991 WL 1783 (E.D. Pa. Jan. 8, 1991) (denying class certification due to individual issues of reliance); *Gross v. Johnson & Johnson-Merck Consumer Pharm. Co*., 696 A.2d 793, 799 (N.J. Super. Ct. Law Div. 1997) (denying class certification because individual issues of proof were implicated by reliance requirements of consumer protection statute); *Caro v. Procter & Gamble Co.*, 22 Cal. Rptr. 2d 419, 432-33 (Cal. Ct. App. 1993) (class certification denied due to predominance of individual issues).

consumer protection claims, while others do not. *See, e.g.*, *Holeman v. Neils*, 803 F. Supp. 237, 242 (D. Ariz. 1992) (holding that reliance is required under Arizona's statute); *Weinberg v. Sun Co.*, 777 A.2d 442, 446 (Pa. 2001) (holding that plaintiff must allege reliance; *i.e.*, that he heard and believed false advertising and made purchase as a result).[13]

Courts have also noted that the consumer fraud laws of the various states contain "[d]ifferences… in judicial interpretations of the requirements for proof of proximate cause between the consumer fraud act violation and the damage claims asserted." *Fink v. Ricoh Corp.*, 365 N.J. Super. 520, 573, 839 A.2d 942, 976 (N.J. Super. Ct. Law Div. 2003). As one court has noted:

> [T]he Court quite likely would be obliged to apply the laws of all fifty states to determine the need for proving such matters as intent, reliance, causation and injury before even addressing the form and extent of any relief that might be appropriate… *it appears entirely probable that even a consumer fraud theory would require individualized proof concerning reliance and causation, which are hornbook elements of a fraud claim, as prerequisites to recovery by many and perhaps most of the members of the alleged class.*

In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 67-68 (S.D.N.Y. 2002) (emphasis added).[14]

Plaintiffs' consumer protection and fraud claims rest on four types of statements and actions by defendants: (1) the listing of TriCor in the "Orange Book," (2) the de-listing of TriCor from the National Drug Data File ("NDDF"), (3) the prosecution of the patents covering TriCor, and (4) non-specific allegations of "sale and advertisement of TriCor." Amended Complaint at

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[13] *See also Smith v. Olympic Bank*, 693 P.2d 92, 96 (Wash. 1985) (holding that the relevant standard is whether defendant's conduct *induced plaintiff to act* or refrain from acting); *In re Bridgestone/Firestone, Inc. Tires Prods. Liab. Litig.*, 155 F. Supp. 2d 1069, 1109 (S.D. Ind. 2001) (making *Erie* prediction that Tennessee would require reliance), *rev'd on other grounds*, 288 F.3d 1012 (7th Cir. 2002).

[14] *See also Andrews v. AT & T Co.*, 95 F.3d 1014, 1025 (11th Cir. 1996) (decertifying class because fraud claims would require plaintiffs "to show, on an individual basis, that they relied on the misrepresentations, suffered injury as a result, and incurred a demonstrable amount of damages"); *Castano v. American. Tobacco Co.*, 84 F.3d 734, 745 (5th Cir. 1996) (recognizing "a fraud class action cannot be certified when individual reliance will be an issue"); *Gunnells v. Health Plan Servs., Inc.*, 348 F.3d 417, 434-35 (4th Cir. 2003) (determining "what information each" consumer "actually had," whether he or she justifiably relied on the fraud alleged, and suffered an injury "almost inevitably" requires "an individualized inquiry").

¶119. However, the putative class representatives admit that they have never seen or heard any TriCor advertising, and that they have never heard of—let alone relied upon—the Orange Book, the NDDF, or any of the patents covering TriCor.[15]

Accordingly, it is difficult to see how class members will prevail in states where the applicable state law requires actual reliance or a casual link between the alleged statement and the harm. Requiring class plaintiffs to prove elements such as reliance where the home states of unnamed class members do not require this element would be unfair to those unnamed class members. Conversely, not requiring class plaintiffs to satisfy the elements required by all states would be equally unfair and prejudicial to defendants. Moreover, subclasses are not a viable solution because they would not eliminate the prejudice to one side or the other in a jury trial.

2. Is the plaintiff a "consumer"?

Many states' statutes bar corporations and unions, like many of the class members here, from bringing claims under their consumer protection or consumer fraud statutes. In *In re Pharmaceutical Industry Average Wholesale Price Litig*., 230 F.R.D. 61 (D. Mass. 2005), the court refused to certify a consumer fraud class of indirect purchasers because plaintiffs had "not examined which state consumer protection statutes, if any, permit corporations, unions, or other entities to bring such class actions. It is apparent that many do not, and those that do have widely varying requirements." *Id*. at 86, *citing Scully Signal Co. v. Joyal*, 881 F.Supp. 727, 741 (D.R.I. 1995) (holding that Rhode Island law bars suits by corporations); *see also Zine v. Chrysler Corp*., 261, 600 N.W.2d 384, 392 (Mich. Ct. App. 1999) (noting that Michigan law allows a corporation to

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bring a consumer protection claim only if it made the challenged purchase for its own use); Tex. Bus & Com. Code § 14.45(4) (allowing suits only by businesses with assets of less than $25 million to bring suits).

Some states bar entities who purchased products "for business purposes," as opposed to purchasing them for household or personal use, from recovering under their consumer fraud statutes. *See, e.g.* Mo. Ann Stat., § 407. 025(1); *Weinberg v. Sun Co., Inc.*, 565 Pa. 612, 618, 777 A.2d 442, 446 (2001) (Pennsylvania consumer fraud statute requires plaintiff in class action suit "to allege he purchased gasoline for personal or household purposes as opposed to business purposes"). In states applying this rule, corporate or union class members which purchased or reimbursed members for TriCor as part of their business activities would be barred from pursuing consumer fraud claims. Accordingly, application of state law will require an individualized inquiry into whether any individual corporate or union purchaser, based on its individual circumstances, is permitted to invoke its state's consumer protection or consumer fraud laws.

3. Actual fraud, deception, or misrepresentation of a material fact.

In some states, plaintiffs must show that defendants acted unfairly or wrongfully with respect to consumers to proceed under a consumer protection statute. In other states, plaintiffs must prove that the defendants engaged in "actual deception" that resulted in consumers being misled. *See* Appendix A.[16] Plaintiffs have not identified a single allegedly fraudulent or misleading claim

[16] *See also Millennium Communications & Fulfillment, Inc. v. Office of Attorney Genera.*, 761 So.2d 1256, 1264 (Fla.App. 3 Dist. 2000*)* (rejecting claim based on act that was not "likely to mislead a consumer acting reasonably under the circumstances") (citation omitted); *Stutman v. Chemical Bank*, 731 N.E.2d 608, 611-12 (N.Y. 2000) ("Whether a representation or an omission, the deceptive practice must be likely to mislead a reasonable consumer acting reasonably under the circumstances.") (citations omitted); *Ganzevoort v. Russell*, 949 S.W.2d 293, 299 (Tenn. 1997); *Robinson v. Avis Rent A Car Sys., Inc.*, 22 P.3d 818, 824 (Wash. Ct. App. 2001) (observing that a practice is unfair or deceptive if it "ha[s] the capacity to deceive a substantial portion of the public"); *Avery v. State Farm Mut. Auto Ins. Co.*, 2005 WL 1981444, at *52 (Ill. Aug. 18, 2005) (holding that the plaintiff in an consumer protection action must show that "he or she was, in some manner, deceived by the misrepresentation").

directed at consumers in their complaint, and the named plaintiffs have testified at their depositions that they never saw or heard the allegedly deceptive statements. *See* Note 13, *supra*. Moreover, the standards as to what constitutes a "misstatement," "deception," or "fraudulent conduct," requires a state-by-state analysis, the application of which, at trial, would be completely unmanageable.

4. Privity or a direct relationship.

Plaintiffs are indirect purchasers[17] but some states' consumer protection statutes require privity or a direct relationship between the plaintiff and the defendant. *See generally Elkins v. Microsoft Corp*., 817 A.2d 9, 19 (Vt. 2002) (noting division of authority and collecting cases). In states with this requirement, plaintiffs' claims will need to be carefully analyzed on an individual basis, to determine whether any individual plaintiff can meet its state's requirement for a privity or other direct relationship.[18]

5. Notice or a pre-suit demand.

Several states require that some form of notice or demand be made to the defendant as a prerequisite to filing suit. *See, e.g.,* Cal. Civ. Code § 1782; *A.B.C. Home & Real Estate Inspection, Inc. v. Plummer*, 500 N.E.2d 1257, 1262-63 (Ind. Ct. App. 1986); Wyo. Stat. Ann. § 40-12-109; Me Rev. Stat. Tit. 5 §213.1-A; Mass Gen Laws Ch. 93A §9(3); Tex. Bus. & Comm. Code §17.45(4). This Court will need to determine if a pre-suit demand, notice, or alternative dispute procedure is required by each state statute, and the fact-finder will need to determine whether the actions by the plaintiffs from those states are sufficient to satisfy this requirement—a highly individualized

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[17] *See, e.g*., Ex. 8 (Wilde Depo.) at 36; Ex. 9 at 40-41; Ex. 7 (Kim Depo.) at 32.

[18] In addition, in some states in which strict privity is not required, the indirect nature of the relationship between the plaintiffs and Abbott and Fournier may make it difficult for the plaintiff to satisfy other elements, such as consumer nexus or causation. *See, e.g., Vacco v. Microsoft Corp*., 793 A.2d 1048, 1064-65 (Conn. 2002) (holding that, although privity is not a requirement, an indirect purchaser may be too remote from the alleged conduct to satisfy causation).

inquiry.[19]

6. Damages issues.

In many states, proof of "actual damages" is required to recover under consumer protection statutes, and state consumer protection laws vary with regard to the appropriate methodologies for calculating such damages. In *Fink v. Ricoh Corp.*, 839 A.2d 942, 980-982 (N.J. Super. Ct. Law Div. 2003), the court provided a detailed analysis of the wide variations in state laws, and concluded that nation-wide certification was not appropriate because of these variations. The same analysis applies here.

While some states permit actual damages to be enhanced, the process and level of proof required varies. Some statutes contain no provision for multiple damages, *see, e.g.*, Fla. Stat. Ann. § 501.211(2), while others provide for automatic trebling, *see, e.g.*, Del. Code Ann. tit. 6, 2533(c); N.J. Stat. Ann. § 56:8-19, and some states permit treble damages only at the discretion of the court. *See, e.g.*, 73 Pa. Cons. Stat. Ann. § 201-9.2(a). Moreover, some states require a showing of an increased level of culpability or violation of notice before multiple damages can be awarded *See e.g.*, *Steed Realty v. Oveisi*, 823 S.W.2d 195, 201 (Tenn. 1991) (holding that Tennessee law requires a showing of knowing or willful acts); Tex. Bus. & Com. Code § 17.50(b)(1) (same). Therefore, the showings that plaintiffs in this case will need to make in order to obtain the highest level of available damages will vary widely from state to state.

B. Even *within* states, an individualized inquiry is required.

Differences *among* state statutes is not the only hurdle. Where, as here, state laws requires a showing of reliance, proof of causation or actual damages, an individualized inquiry as to

[19] In addition, in some states, parties to a consumer fraud case are entitled to a trial by jury. *See, e.g., Zorba Contractors, Inc. v. Housing Authority*, 362 N.J. Super. 124, 827 A.2d 313 (N.J. App. Div. 2003); *Waggener v. Seever Systems, Inc.*, 233 Kan. 517, 664 P.2d 813 (1983). In other states, they are not. See, *e.g., Martin v. Heinold Commodities, Inc.*, 163 Ill.2d 33, 205 Ill. Dec. 443, 643 N.E.2d 734 (1994); *Travis v. McDonald*, 397 Mass. 230, 490 N.E.2d 1169 (1986).

each alleged claimant *within any given state* will be necessary. *See, e.g., Newman v. RCN Teleco. Services, Inc.*, No. Civ. A 4816, 2006 WL 572345 at *11 (S.D.N.Y. March 7, 2006) (denying certification of a class of New York consumers because "*each* plaintiff will have to show that [defendant's] disclosures… were inadequate, thus *deceiving* plaintiffs…this showing will require an *individualized inquiry into many different issues*").

Fraud cases have been singled out as inappropriate for class actions based on their required showing of reliance by the Advisory Committee Notes to Rule 23(b)(3), which provide that "although having some common core, a fraud case may be unsuited for treatment as a class action if there was material variation in the representations made *or in the kinds or degrees of reliance* by the persons to whom they were addressed." (emphasis added).

* * *

As a result of these differences among the relevant states statutes, the proposed class cannot satisfy the requirements of Rule 23.

III. PLAINTIFFS' PROPOSED 51-STATE UNJUST ENRICHMENT CLASS DOES NOT SATISFY RULE 23

"Unjust enrichment" is an inherently malleable common law doctrine, designed to offer relief from the harsh results sometimes produced under the law of contracts. *Jordan Keys & Jessamy, LLP v. St. Paul Fire and Marine Ins. Co.*, 870 A.2d 58, 63 (D.C. 2005). As a result of its flexible nature, the doctrine of unjust enrichment has developed with different elements and offers different relief among the states. For example, the states do not agree whether "no adequate remedy at law" is a required element to state a claim of unjust enrichment. *Contrast Total Care Physicians P.A. v. O'Hara*, 798 A.2d 1043, 1056 (Del. Sup. Ct. 2001) (finding the equitable remedy of unjust enrichment available only where there is no adequate remedy of law) *with Webon Group, Inc. v. S.M. Props, L.P.*, 1 S.W.3d 538 (Mo. Ct. App. 1999) (allowing invocation of equitable principles in spite of an adequate remedy at law).

Moreover, the case law recognizes at least two forms of restitution based on unjust enrichment: "parasitic" unjust enrichment, and "freestanding" unjust enrichment. *See In re New Motor Vehicles Canadian Export Antitrust Litig.*, 350 F.Supp. 2d 160, 207-212 (D. Maine 2004) ("[A] claim for freestanding or autonomous restitution in the context of behavior regulated by an independent body of law (here, antitrust and consumer protection statutes) is 'more nettlesome' than a parasitic claim."). Freestanding unjust enrichment is not allowed in some states for conduct regulated by an independent body of law, such as antitrust law. *See, e.g, Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936-37 (3d Cir. 1999). But other states allow for recovery on an unjust enrichment claim even where the underlying conduct is not violative of the law of the field. *See, e.g. In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 669 (E.D. Mich. 2000).

Attached as Appendix B is a chart detailing the differences among the various state unjust enrichment laws. Because the law and jurisprudence of unjust enrichment varies widely from state to state, numerous courts have recognized that common-law unjust enrichment claims are not susceptible to class treatment because of the predominance of individual issues and manageability issues. *See, e.g. Clay v. American Tobacco Co.*, 188 F.R.D. at 501 (S.D. Ill. 1999) (denying class certification for a claim of unjust enrichment because such a claim is "packed with individual issues and would be unmanageable").

A. Indirect purchasers are not entitled to pursue unjust enrichment claims in many states.

Some states' courts have held that many indirect purchasers are not entitled to bring unjust enrichment claims at all. In states where indirect purchasers are barred from asserting antitrust claims, an unjust enrichment claim may not be pursued as a means of recovery for what is

essentially an antitrust injury. *In re New Motor Vehicles,* 350 F. Supp. 2d at 211-212.[20] Accordingly, this Court will have to determine on a state-by-state basis whether each of the twenty-seven states that currently bar indirect purchasers from recovery on an antitrust theory would permit those same purchasers to recast their claims as "unjust enrichment" claims and recover damages on that basis.[21] In States where the state's highest court has not spoken on the issue, this Court will have to make *Erie* determinations as to the likely result under each state's law.

B. Differences in state law preclude class treatment.

In addition to the baseline questions of whether plaintiffs from a particular state are entitled to plead claims for unjust enrichment *at all*, there exist a wide variety of differences in state unjust enrichment laws—differences both substantial and subtle—that render such multi-state claims wholly inappropriate for class treatment. *Clay v. American Tobacco Co.*, 188 F.R.D. at 501 (S.D. Ill. 1999); *Harvell v. Goodyear Tire & Rubber Co.*, No. 102 128, 2006 WL 1073067, at *4 (Okla. Apr. 25, 2006) ("The elements of unjust enrichment claims differ markedly from state to state… state considerations of such claims differ over issues of misconduct, availability of adequate

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[20] Numerous other courts have applied the same rule. *See, e.g., In re Terazosin Hydrochloride Antitrust Litig.*, 160 F.Supp. 2d 1365, 1379-80 (S.D. Fla. 2001); *In re Microsoft Corp. Antitrust Litig.*, 241 F.Supp.2d 563, 565 (D. Md. 2003) (interpreting Kentucky law to prevent indirect purchasers from recovering on their unjust enrichment claim for antitrust violations where they could not recover under state antitrust law); *Aikens v. Microsoft Corp.*, 159 Fed. Appx. 471, 447, (2005 WL 3439552) (4th Cir. 2005) ("as indirect purchasers… the plaintiffs cannot sue to recover monetary damages under Louisiana antitrust law… to the extent that the plaintiffs cannot sue for monetary damages under Louisiana antitrust law, they cannot employ a subsidiary unjust enrichment claim to circumvent this rule."); *Stutzle v. Rhone-Poulenc S.A.*, NO. 002768 OCT.TERM 2002, 2003 WL 22250424, at *2 (Pa. Com. Pl. Sept. 26, 2003) (holding that "to allow plaintiffs to use a claim for unjust enrichment as a means for collecting damages which are not allowable by Pennsylvania's antitrust law, is not a proper use of the claim"); *In re Microsoft Corp. Antitrust Litig.*, 401 F.Supp. 2d 461, 464 (D. Md. 2005) ("Plaintiff attempts to circumvent South Carolina's rule that indirect purchasers may not recover under state antitrust laws by recasting his claim as a common law claim for 'unjust enrichment'… the specific bar on indirect purchaser recovery incorporated into South Carolina's antitrust statutes prohibits Plaintiff's general common-law claim.").

[21] *See generally* Gerald E. Hawxhurst, *A State-By-State Look At The Law On Indirect Purchaser Damage Actions, Competition,* Vo. 15, No. 1, Spring/Summer 2006.

remedies at law, and the effect of the existence of an express contract governing the transaction.").[22]

The chart attached hereto as Appendix B demonstrates the myriad differences between the laws of unjust enrichment in the fifty-one jurisdictions in which those claims are presented. For example:

- Some states require a "direct" relationship, or privity, between plaintiff and defendant. *See, e.g., In re Vitamins Antitrust Litig.*, 2001 WL 849928 (D.D.C. Apr. 11, 2001) (applying Tennessee law); *Stutzle*, 2003 WL 22250424 at *1, (Pa. Com. Pl. September 26, 2003) ("any unjust enrichment claim would belong to the direct purchasers, not to indirect purchasers such as plaintiffs").
- Some states require that defendant "appreciates" or "knows" of the benefit retained, while other states require merely that defendant receive a benefit, even without any wrongdoing on the part of the defendant. *See e.g., State Dept. of Revenue Child Support Enforcement Div. v. Wetherelt*, 931 P. 2d 383 (Alaska 1997); *Florida Power Corp. v. City of Winter Park*, 887 So. 2d 1237 (Fl. 2004) (accord); *BHA Inv., Inc. v. State*, 138 Idaho 348, 355 (2003) (accord); *Haz-Mat Response, Inc. v. Certified Waste Servs., Ltd.*, 259 Kan. 166, 910 P.2d 839 (1996). Some states reverse this calculus, holding that the plaintiff must have conferred a benefit on the defendant unwillingly. *See Ringier Am., Inc. v. Land O'Lakes, Inc.*, 106 F.3d 825, 829 (8th Cir 1997) (applying Minnesota law).
- Some states require plaintiff to prove "clean hands" prior to recovery on an unjust enrichment theory. *Dennett v. Kuenzli*, 130 Idaho 21, 936 P.2d 219, 225 (1997). Under some circumstances, plaintiffs are required to provide notice and an opportunity for plaintiff to cure prior to bringing a claim for unjust enrichment. *See First Nationwide Savings v. Perry*, 11 Cal. App. 4th 1657, 1668, (Cal. 1992) ("A person's notice of the circumstances giving rise to unjust enrichment affects that person's obligation to make restitution."); *Keller v. O'Brien*, 425 Mass. 774, 780-81 (Mass. 1997); *Freeman Industries, LLC v. Eastman*

[22] *See also Davis v. Lenox Hill Hosp.*, No. 03 Civ. 3746 DLC, 2004 WL 1926086, at * 5 (S.D.N.Y. Aug. 31, 2004) (denying class certification where unjust enrichment claims did not present "common issues of law or fact with respect to members of the purported class"); *In re Rezulin Prods. Liability Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (holding class treatment of unjust enrichment claims inappropriate); *cf. Granito v. IBM*, 2003 WL 1963161 at *2 (Conn. Super. Ct. Apr. 16, 2003) (absent the conferring of a benefit by the plaintiff directly, no action for unjust enrichment by him is valid). *O'Brien v. J.I. Kislak Mortgage Corp.*, 934 F. Supp. 1348, 1359 (S.D. Fla. 1996) (denying motion to certify unjust enrichment claim because of "commonality problems"); *Avis Rent A Car Sys., Inc. v. Heilman*, 876 So.2d 1111, 1123 (Ala. 2003) (holding that unjust enrichment claims are not suitable for class treatment); *Hutson v. Rexall Sundown, Inc.*, 837 So. 2d 1090, 1093 (Fla. Dist. Ct. App. 2003) (affirming denial of class certification on unjust enrichment claims which "depend[ed] upon resolutions of predominant individualized fact issues") ; *Davis*, 2004 WL 1926086, at * 5 (unreported decision) (denying class certification where unjust enrichment claims did not present "common issues of law or fact with respect to members of the purported class"); *In re Rezulin*, 210 F.R.D. at 68-69 (holding class treatment of unjust enrichment claims inappropriate).

Chemical Co., 172 S.W.3d 512, 525-26 (Tenn. 2005) (requiring a plaintiff to demonstrate exhaustion of remedies at law) (citations omitted).

- In some states, unjust enrichment is available in addition to a claim on an express contract, while in many states such a claim is forbidden. *Compare Johnson v. American Nat'l Ins. Co.*, 126 Ariz. 219, 613 P.2d 1275 (Ariz. App. 1980) (disallowing recovery under a theory of unjust enrichment where relationship of the parties is governed by a contract); *Benefit Trust Life Ins. Co. v. Union Nat'l. Bank of Pittsburgh*, 776 F. 2d 1174 (3d Cir. 1985) *with Hixon v. Allphin*, 76 Idaho 327, 281 P.2d 1042 (1955) (holding unjust enrichment claim may proceed even if parties are subject to an express contract).
- Different statutes of limitation apply in different states. For example, Texas and California both have two-year statutes. *See Singer v. City of Waco,* 324 F.3d 813, 826 (5th Cir. 2003); Cal. Code Civ. Proc. § 339. But other states provide for a longer statute of limitations for unjust enrichment claims. *See e.g., Evans v. Evans*, 237, 228 S.E. 2d 857, 860 (Ga. 1976).

These differences in the laws are not merely technical, but go to the heart of a plaintiff's right to bring such a claim.[23] They create individualized legal and factual issues that predominate over the common issues, and render a class action unmanageable.

IV. PLAINTIFFS HAVE NOT DEMONSTRATED THE ADEQUACY OF THE CLASS REPRESENTATIVES.

The adequacy requirement is intended to ensure that the claims of the named representatives are the same as those of the absent class members. *In re General Motors Corp. Pick-up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 784 (1995), *aff'd*, 134 F.3d 133 (3d Cir. 1998) ("The protection of the absentees' due process rights depends in part… on the extent that the class representatives have interests that are sufficiently aligned with the absentees to assure that the

[23] Nor may this court ignore the differences between the state laws and apply a single standard to the class as a whole or to groupings of states in subclasses. "Courts must respect differences [in state laws] rather than apply one state's laws to sales in other states with different rules." *In re Bridgestone/ Firestone, Inc.*, 288 F.3d 1012, 1018 (7th Cir. 2002); citing *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 568-73 (1996); *Castano v. American Tobacco Co.*, 84 F.3d 734, 740-41 (5th Cir. 1996) (finding that the district court erred in failing to consider how variations in state law affect predominance and superiority) ("In a multi-state class action, variations in state law may swamp any common issues and defeat predominance"), citing *Georgine v. Amchem Prods, Inc.*, 83 F.3d 610, 618 (3d Cir. 1996) *aff'd*, 521 U.S. 591 (1997). And Plaintiffs have not provided any plan for dealing with the differences in state unjust enrichment law on a class-wide basis. *See, e.g. Auscape Int'l. v. National Geographic Enterprises, Inc.*, 2003 WL 23531750, at *16 (S.D.N.Y. July 25 2003) (internal citations omitted) ("plaintiffs b[ore] the burden of providing an extensive analysis of state law variations to determine whether there are insuperable obstacles to class certification… [a]ttempts at such extensive analysis often include model jury instructions and verdicts forms").

monitoring serves the interests of the class as a whole."). Therefore, the rule requires that the class representatives will make the same factual and legal arguments as the absent members of the class.

Here, named plaintiffs from only nine states propose to represent a class comprising both organizational and individual indirect purchasers from all 51 states (for plaintiffs' unjust enrichment claims), 43 states (for plaintiffs' consumer protection claims), and 23 states (for the state-law antitrust claims). But the elements, case law, and jurisprudential considerations that apply to each of these claims differ vastly from state to state. The result is an inherent and serious risk of prejudice either to absent class members or to the defendants, exemplified by the failure of many named plaintiffs to give testimony sufficient to establish reliance on any of the alleged fraudulent actions, statements or representations made by defendants, or sufficient to demonstrate that the actions of the defendants caused them to purchase TriCor instead of an available alternative like a statin, Lofibra, Gemfibrozil, Antara or Triglide.[24] Because the named representatives cannot adequately present the state-law claims of absent class members, this class should not be certified. *See, e.g., In re Ford Motor Co. Bronco II Prod. Liab. Litig.*, 177 F.R.D. 360, 367-68 (E.D. La. 1997) (adequacy of representation was not met where the named plaintiffs were only from 9 of the 51 jurisdictions in which they alleged a cause of action).[25]

V. PLAINTIFFS' PROPOSED CLASS BASED ON STATE ANTITRUST CLAIMS DOES NOT SATISFY RULE 23.

Plaintiffs seek to certify a class based on the state antitrust laws of the 23 states in which indirect purchasers have been permitted to bring antitrust damage claims otherwise barred under

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[24] *See, e.g.*, Ex. 7 (Kim Depo.) at 27-33; Ex. 8 (Wilde Depo.) at 32, 34-36; and Ex. 9 (Shain Depo.) at 39-41).

[25] *See also Nicodemus v. Union Pacific Corp.*, 204 F.R.D. 479, 491 (D. Wyo. 2001), *rev'd on other grounds*, 440 F.3d 1227 (10th Cir. 2006) (holding that a class representative from only one state could not satisfy the adequacy requirement in representing absent plaintiffs from 21 other jurisdictions); *In re Relafen*, 225 F.R.D. at 22 (rejecting proposed class settlement because as a result of differences in state laws, the court could not be assured that the absent class members received "fair and adequate representation").

federal law. Permitting indirect purchaser suits under different state laws is one thing; certifying a class based on the particular facts of this case is another. Where, as in the present case, the issue of injury or damages does not "lend itself to such a mechanical calculation, but requires separate mini-trials of an overwhelming large number of individual claims," courts have found that class certification should be denied. *Windham v. Am. Brands, Inc.*, 565 F.2d 59, 68-69 (4th Cir. 1977) (summarizing cases); *see also Lienhart v. Dryvit Sys., Inc.*, 255 F.3d 138, 147 (4th Cir. 2001) ("[I]t is impermissible to determine damages on a classwide basis in order to facilitate class treatment of a case when the governing law requires individualized proof of damages.").

A. Individualized Issues as to Injury Predominate Because Plaintiffs Cannot Demonstrate on a Class-wide Basis That The Alleged Overcharge was "Passed-through" to Them.

To demonstrate injury under state antitrust laws, plaintiffs must prove actual injury.[26] *See Crouch v. Crompton Corp.*, 2004 WL 2414027, at *25 (N.C. Super. Ct. Oct. 28, 2004) ("Unlike direct purchasers who may recover for costs which they do not incur, state indirect purchasers may recover only for injury actually incurred."). Because the indirect plaintiffs did not purchase the product from Abbott and Fournier at an alleged "overcharge" price, they must show that the direct purchaser or purchasers from whom they bought the product "passed through" the overcharge. *See id.* ("Thus, they must prove pass through of the artificially inflated cost.").

If the overcharge was absorbed by a purchaser at a higher level of the distribution chain prior to reaching a specific plaintiff, that plaintiff has not suffered "actual injury" and does not have an antitrust (or other state law) claim. *In re Brand Name Prescription Drug Antitrust Litig.*, Nos. 94C897, 1994 WL 663590, at *7 (N.D. Ill. Nov. 18, 1994) (finding that indirect purchaser plaintiffs failed to show that they could establish the fact of injury and damages: "whether a particular consumer has in fact been injured will depend entirely upon whether the alleged conspiracy resulted

[26] The same holds true for plaintiffs' fraud and unjust enrichment claims.

in overcharges that were 'passed on' to that consumer by retailers and others in the chain of distribution").[27,28]

Plaintiffs' analysis merely assumes that the inflated price allegedly charged to direct purchasers was "passed through" to them, and that therefore they suffered injury. But this generalized conclusion is not sufficient to satisfy their burden of demonstrating actual injury on a class-wide basis. *See Derzon v. Appleton Papers, Inc*., No. 96-CV-3678, 1998 WL 1031504, at *8, 1998-2 Trade Cases P 72,300 (Wis. Cir. Ct. July 7, 1998) ("[c]onstructing economic models in order to reach generalized conclusion about economic behavior is one thing; using such theories to prove that every class member has suffered a loss and the amount of that loss is quite another."). Plaintiffs will have to prove, on an individual basis, that each plaintiff was injured – in other words, paid a price that was inflated by virtue of the "pass-through" of an improper overcharge.[29] They have provided no methodology for doing so. For this reason, plaintiffs' motion for class

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[27] *Gordon v. Microsoft Corp*., 2003 WL 23105552, at *4, 2004-1 Trade Cases P 74,272 (Minn. Dist. Ct. Mar. 14, 2003) ("Plaintiffs have the burden…of *showing that pass through occurred*"); *Melnick v. Microsoft Corp*., No. V-99-709, CV-99-752, 2001 WL 1012261 at *4 n. 5, 2001-2 Trade Cases P 73,408 (Me. Super. Ct. Aug. 24, 2001) (collecting state cases rejecting class certification because varying degrees of pass-through precluded findings of class-wide injury); *Execu-Tech Bus. Sys., Inc. v. Appleton Papers, Inc*., 743 So.2d 19, 20 (Fla. Dist. Ct. App. 1999) (holding that the existence of variability in the amount of pass through throughout the distribution chain during the class period precluded proving impact and damages in common); *A & M Supply Co. v. Microsoft Corp*., 252 Mich. App. 580, 625-26, (2002) (collecting cases denying class certification to indirect purchasers because plaintiffs had failed to demonstrate that overcharges had been passed through to them, and could not therefore prove injury or damages on a class-wide basis).

[28] Commentators have noted that differences in state-law injury and standing requirements, along with differing jurisprudential approaches to "pass-through" arguments in various states, create uncertainty as to the proper treatment of class plaintiffs' claims. "Resolving the pass-through dilemma implicates competing considerations of fairness, practicality, and deterrence of antitrust violations. The judiciaries and legislatures of the United States and of the various states have reached different conclusions that have resulted in varying and sometimes uncertain antitrust liability regimes in different jurisdictions." Joseph Angland et al, *Practising Law Institute: Procedural Aspects Of Private Antitrust Litigation*, 633, 649 (February 2006).

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certification should be denied.

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In *Derzon*, the court refused to certify a class because the class expert's methodologies failed to show how any increase to the distributor would have been passed on to the purchaser. *Derzon*,1998 WL 1031504, at *7, and numerous other courts have refused to certify a class action because the economic methodology was insufficient to accurately determine pass-on damages. *See, e.g. Wood v. Abbott Labs.*, 1997 WL 824019, at *2 (Mich. Cir. Ct. 1997) (class certification denied when expert assumed that each pharmacy acted optimally, when in reality each pharmacy would have handled pass-on damages in a different manner).[30]

Plaintiffs' expert ignores the complex, multi-level negotiations that bear on the "price" any class member paid for TriCor. *See* Ex. 2 (Navarro Report) at ¶¶ 33-44, 66-111. The "price" is the product of the relative economic bargaining power of the entities involved at each level that will differ from health plan to health plan and involve factors wholly unrelated to TriCor itself. *See* discussion *supra* at 10-12.

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[30] *See also A & M Supply Co.*, 252 Mich. App. at 640 (class certification denied where plaintiffs failed to provide formula for calculating pass-on amount); *Derzon*,1998 WL 1031504, at *7 (class certification denied where the expert's use of incidence or regression analysis was insufficient to show pass-on damages); *Execu-Tech*., 743 So. 2d at 21, (class certification denied where expert's use of incidence analysis was insufficient to show damages impact on the proposed class); *In re Methionine*, 2003 WL 22048232 (decertified class action where economic formula proposed by expert did not take into account the many variables needed to determine the pass-on amount); *Melnick*, 2001 WL 1012261 *at* *16, (denying class certification where the plaintiffs' expert report did not specify that the proposed method would work for an indirect purchaser, and where the expert did not determine if the market or geography affected the amount of pass-on); *Peridot, Inc. v. Kimberly-Clark Corp.*, 2000 WL 673933 at *5, 2000-1 Trade Cases P 72,816 (Minn. Dist. Ct. Feb. 7, 2000) (denying class certification where the expert did not create a model for discussing any price increase that was passed through to indirect purchasers).

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This deficiency, in and if itself, is sufficient to defeat certification. *See A &M Supply Co*., 252 Mich. App. at 619-20 (refusing to certify a class where the expert opinion chose to calculate an aggregate difference instead of calculating "how much overcharge was passed-on to each individual class member.").

An attempt to prove the amount by which each class member was damaged suffers from the same problem. Plaintiffs' state antitrust law claims are subject to the same requirement that the plaintiffs prove that damages are susceptible to class-wide proof. *City of St. Paul v. FMC Corp.*, No. 3-89-0466, 1990 WL 259683, at *2, 1990-2 Trade Cases P 69,283 (D. Minn. Nov. 14, 1990); *Derzon*, 1998 WL 1031504, at *4 (Wis. Cir. Jul 7, 1998). As a result, many courts in have refused to certify classes of indirect purchasers because it is impossible to determine damages on a class-wide basis, even though the repealer statutes grant standing to indirect purchasers. *See In re Brand Name Prescription Drugs*, 1994 WL 663590 (applying Alabama Law) (refusing to certify a class of indirect purchasers of prescription drugs despite holding that indirect purchaser plaintiffs have standing).[32] Moreover, courts have cited the complexity of the supply chain for prescription drugs

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[31] *See* discussion of price variability *supra* at pp. 10-13.

[32] *See also McCarter v. Abbott Labs, Inc.*, No. CV-91-050, 1993 WL 13011463 (Ala. Cir. Ct. Apr. 14, 1993) (*same*); *Execu-Tech*., 743 So. 2d at 22 (Fla. App. 4 Dist. 1999) (refusing to certify a class of indirect consumers); *Melnick*, 2001 WL 1012261; *Ren v. Philip Morris Inc*., No. 00-004035-CZ, 2002 WL 1839983 (Mich Cir. Ct. June 11, 2002) (refusing to certify a class of indirect purchasers because plaintiff could not use economic theory to establish pass-on of overcharge); *Keating v. Philip Morris, Inc.*, 417 N.W.2d 132, 136-37 (Minn. Ct. App. 1987) (holding that a class action was inappropriate because "proof of damages would result in thousands of mini-trials."), *City of St. Paul*, 1990 WL 259683, at *2 (holding that "despite the viability of indirect-purchaser claims under state law, [it] is not

(continued . . .)

and the attendant difficulties in determining injury or damages for any individual indirect purchaser in refusing to certify classes. *Kerr v. Abbott Labs*, No. 96-002837, 1997 WL 314419, 1997-1 Trade Cases P 71,776 (Minn. Dist. Ct. Feb. 19, 1997) ("Tracing individualized transactions through the complex distribution network of the brand-name prescription drug industry would clearly cause individual questions of fact to predominate over questions common to the proposed class.")[33] In this case, as described *supra* at pages 10-12, there are profound differences among the prices paid by the widely different members of the proposed class.

Predominance can be destroyed by the presence of individualized issues regarding damages that would require a large number of separate "mini-trials." *See, e.g., Windham v. Am. Brands, Inc.*, 565 F.2d 59, 69 (4th Cir. 1977) ("[W]here the issue of damages and impact does not lend itself to… a mechanical calculation, but requires 'separate' mini-trial(s) of an overwhelming large number of individual claims, courts have found that the 'staggering problems of logistics' thus created 'make [the] damage aspect of (the case) predominate', and render the case unmanageable as a class action").[34, 35]

(. . . continued)
appropriate for class certification" because "individual questions regarding fact of damages . . . render a class action unworkable")

[33] S*ee also In re: Brand Name Prescription Drugs Antitrust Litig.*, 1994 WL 663590. That is because each retailer determines its own prices, which are affected by rebates or discounts, as well as each retailer's business model and margins. *See Peridot, Inc*, 2000 WL 673933, at *4. "This is especially true when the distributors use non-uniform discounts and pricing." *Id.*; *see also Wood v. Abbott Labs.*, 1997 WL 824019, at *2 (refusing to certify a class of indirect purchasers of prescription drugs because there was variation in the approach of different retailers to pass-on any alleged overcharges).

[34] *Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331, 342-43 (4th Cir. 1998) (noting that the Court had denied class certification in antitrust cases because "proof of damages was 'always strictly individualized,'" and that "'[g]eneralized or class-wide proof of damages'" was inappropriate "because proof of actual, individual damages was a critical element of a plaintiff's antitrust claim"); *Montgomery v. New Piper Aircraft, Inc.*, 209 F.R.D. 221, 229 (S.D. Fla. 2002) (denying certification where plaintiffs had not demonstrated that they could prove actual damages without devolving into individualized inquiries, and holding that "the individual damages inherent in this action preclude predominance on two levels, because, even for those putative class members who may have suffered some degree of injury, a

(continued . . .)

Finally, the assertion that individualized issues of damages can be determined at a future stage of the case is improper, since it ignores the requirements of the federal rules and, as one court has noted, would "merely delay[] resolution of the problem until a later date." *Windham,* at 73 (citations omitted). Even where liability and damages are bifurcated, "the problem of determining the fact and amount of damage" for each indirect purchaser remains, and is simply delayed until later in the proceeding. *Keating*, 417 N.W.2d at 138.

B. The Facts Alleged Do Not Support an Overcharge Theory of Damages.

An overcharge approach to proving classwide damages rests on the premise that in the "but for" world each class member would have bought the same product at a lower price. Under plaintiffs' theory, absent defendants' introduction of new TriCor formulations and alleged "bad faith" litigation, defendants' AB-rated generics of the original 200 mg TriCor would have cannibalized TriCor sales, and fenofibrate would have become a low-priced commodity drug in 2002. REDACTED

(. . . continued)
case-by-case factual inquiry is necessary to determine the quantum of damages for each of those putative class members")

[35] Plaintiffs have provided no indication that they will be able to determine the actual damages of any individual plaintiff at any stage of this litigation. Therefore, aggregate damages are not appropriate. *See, e.g., In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 526 (S.D.N.Y. 1996) "[d]amages in an antitrust class action may be determined on a classwide, or aggregate, basis… where the computerized records of the particular industry, supplemented by claims forms, provide a means to distribute damages to injured class members in the amount of their respective damages."); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 350 (E.D.Mich. 2001) (allowing aggregate damages calculations where plaintiffs' expert stated that "computerized records of relevant drug purchases are available to be used along with the proposed damage methodology, formulaic calculation, and detailed claims forms as a means to distribute to injured class members an amount reflecting their actual damages.") To the contrary, Dr. King relies upon IMS data, which he admits provides only an average price over certain defined areas, such as statewide or by metropolitan area. See Ex. 10, C. King Depo. at 60-62.

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Plaintiffs' overcharge theory tries to have it both ways. Plaintiffs assume AB-rated generics would have been quickly adopted in Spring 2002 and taken most of TriCor's share of the market. But plaintiffs "but for" model assumes that fenofibrate utilization would have continued to *increase*, resulting in the same number of fenofibrate prescriptions (branded TriCor plus its AB-rated generics) in 2005 as the more than 10 million TriCor prescriptions in the actual world – more than a twofold increase. Yet, in plaintiffs' "but for" world this increase would not have occurred because, as plaintiffs' expert assumes, no one would have been aggressively promoting fenofibrate.

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On these facts, an overcharge theory has no applicability – either to the purchases in the "but for" world that would have been made of different drugs, such as statins (which already account for over 80% of the dyslipidemia market) or to the purchases that would have been made of AB-rated generics. As an economic matter, neither the statins nor the AB-rated generics of the "but for" world are "fungible" with branded TriCor of the actual world. REDACTED

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C. Plaintiffs Cannot Satisfy the "Predominance" Requirement Because Individualized Issues as to the Injury and Damages Predominate Over Common Issues.

In this case, profound economic differences among the class members will lead to of "mini-trials" to determine whether a class member has been injured and, if so, the appropriate amount of damages for each class members. *See, e.g., Windham*, 565 F.2d at 69; *Broussard*, 155 F.3d at 342-43. The proposed class comprises a broad variety of individuals and entities, who pay widely different prices for TriCor, and whose actual injury and damages are therefore impossible to calculate on an "aggregate" or average basis.

Moreover, the class includes both individual patients—who pay different retail prices for TriCor—as well as "entity" plaintiffs like managed care plans, union benefit plans, and self-insuring employers. Each of these "entity" plaintiffs operates under a different business model. As

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For self-insured entity plaintiffs, the prices paid are determined by many varied and complex models, negotiated discounts, and other models. These differences are meaningful because they affect the ability of each individual plaintiff to demonstrate injury and to prove the amount, if any, that is allegedly "overpaid" for TriCor.

Moreover, the damages of each plaintiff in the class will need to be evaluated with reference to the non-conspiratorial factors affecting the price that plaintiff allegedly "overpaid" for TriCor—factors that differ plaintiff-to-plaintiff and even within groups of the same type of

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[36] REDACTED

plaintiffs.[37] In *Continental Orthopedic Appliances, Inc. v. Health Ins. Plan of Greater New York, Inc.*, 198 F.R.D. 41, 46-48 (E.D.N.Y. 2000), the court explained that the existence of such non-conspiratorial factors precluded class certification where those differences—as here—necessitated individualized inquiry:

> At this stage of the proceedings… the plaintiffs cannot offer common proof establishing that but for the antitrust violation, they would not have suffered their injuries. *In this litigation, neither the services or their distributors are standard. Rather, the class includes businesses of all sizes, each of which was in a different financial position at the time of the alleged violation.* Thus, the alleged damages suffered by the [plaintiffs] could be the result of any number of factors.
>
> …The amount of damages suffered by each plaintiff will depend on a variety of factors, including the types of services and devices the business provided; the geographic location of the business; the number of [defendant's] patients the business served… In addition, the defendants intend to introduce evidence that some plaintiffs never attempted to mitigate their damages…
>
> In sum, although this suit involves allegations of a common antitrust violation, it also involves highly individualized issues of both injury and damages. The individualized issues so overwhelm the common ones that the predominance requirement of Rule 23(b)(3) is not met.

Id. at 47-48 (emphasis added). The same analysis applies here. Because plaintiffs have not proposed a class-wide methodology that accounts for the relevant non-conspiratorial factors in the price that was paid by various class members, class certification should be denied.

VI. WITH RESPECT TO ALL THEIR CLAIMS, PLAINTIFFS HAVE NOT DEMONSTRATED THAT A CLASS ACTION WILL BE "MANAGEABLE"

Plaintiffs have failed to carry their burden of showing that an analysis of three distinct areas of state law of all 51 states will not create insurmountable management issues. *In re LifeUSA Holding*, 242 F.3d at 148 n.13; *Karnuth v. Rodale, Inc.*, No. Civ. A. 03-742, 2005 WL 1683605, at *5 (W.D.Va. July 18, 2005) (denying certification because plaintiffs "failed to address the variations among applicable consumer fraud statutes" creating "an insuperable obstacle"); *Wall v.*

[37] See discussion of pricing practices at pp. 10-13 *supra*; Ex. 2 (Navarro Report) at ¶¶61-111.

Merrill Lynch, Pierce, Fenner & Smith, No. 92C1642, 1992 WL 245540 at *4 (N.D.Ill. 1992) ("It would be unmanageable to consider potentially 50 different state statutes (or perhaps more if some states have more than one applicable statute)").[38]

Where a class is proposed in which the laws of 50 states must be applied, "Plaintiff[s] must provide an 'extensive analysis' of state law variations to determine whether there are 'insuperable obstacles' to class certification." *Karnuth*, 2005 WL 1683605, at *4; *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 453 (D.N.J. 1998). Plaintiffs have not provided such an "extensive analysis," which requires affirmative methodologies for addressing the differences in application of state laws, not simply a blanket assertion that the differences are addressable. *See In re Ford Motor*, 174 F.R.D. at 350, 356 (holding that plaintiffs must provide a "blueprint" demonstrating how case could be presented to the jury without "overwhelming jurors with hundreds of interrogatories and a verdict form as long as an almanac"); *see also Castano*, 84 F.3d at 742 (holding that "assurances of counsel" that a case will be manageable are not sufficient).

Plaintiffs predict that "any variation among the legal standards can be readily handled by appropriate instructions and questions to the jury. Jury instructions can be patterned to account for variations in state law and special verdict forms can be used to address those variations." Plaintiff's Mot. P. at 34. But the case on which plaintiffs rely, *School Asbestos*, is a case study in unmanageability. While a class was certified in that case, it has been cited by other Circuits as an example of the utter impracticality of the class action mechanism in this type of case: "[a]lmost nine years after the first complaint was filed [in *School Asbestos*], and eight years after the court of appeals had affirmed certification, the conflict of law issues had yet to be resolved." *Castano*, 84 F.3d at 751 (discussing *School Asbestos*).

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[38] As demonstrated in Defendants' Consumer Protection Chart at Appendix A, many states do have multiple applicable statutes.

Moreover, courts have rejected conclusory assertions like those made by the plaintiffs here that sub-classes or special verdict forms can be used to eliminate serious issues of inconsistent state laws. In *Chin v. Chrysler Corp.*, the court denied certification, noting that the plaintiffs had "fail[ed] to meet their burden of setting forth a workable plan for dealing with these issues at trial"—despite submitting a 50-state survey—instead "merely assert[ing]" that the case could be managed through the use of subclasses, jury interrogatories, and special verdict forms. *Id.* at 463. In sum, plaintiffs have provided no proposal for the management of this class—a class of diverse plaintiffs, suing under diverse and varied state laws.

VII. THE CLASS ACTION MECHANISM IS NOT NECESSARY TO ADDRESS INJUNCTIVE RELIEF IF SUCH RELIEF IS WARRANTED.

With respect to plaintiffs' injunctive claims, a class action is not superior to other methods of adjudication, because the nature of the relief that plaintiffs seek is such that any relief obtained by one consumer in a single action (or a competitor or class of direct purchasers) would inure to the benefit of all indirect purchasers, and therefore a class action, with its attendant complexities, cost, and delay, provides no additional benefit.

The injunctive relief plaintiffs seek is directed towards Abbott and Fournier's general conduct, not towards actions taken towards members of the class individually. Courts have recognized that where the precise relief sought by a class is likely to be obtained by traditional bipolar litigation, the complexity, expense and burden of a class action is not required. *See Access Now, Inc. v. Walt Disney World Co.*, 211 F.R.D. 452, 455 (M.D. Fla. 2001) ("[t]he complexity and expense of a class action is not necessary" where "plaintiffs may achieve by injunction all relief which would inure to similarly situated persons").[39]

[39] *Kow v. New York City Hous. Auth.*, 92 F.R.D. 73, 74 (D.C.N.Y. 1981) (there is no benefit to having a class when "there is no reason to doubt that the defendants would accord to all members of the proposed class the benefits of any judgment accorded to the plaintiff.") (internal citations omitted); *Dionne v.*

(continued . . .)

Because class treatment is not necessary to obtain injunctive relief that will inure to the benefit of the class as a whole, certification of plaintiffs' claims for injunctive relief should be denied.[40]

CONCLUSION

For the reasons set forth above, plaintiffs' motion for class certification should be denied.

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Bouley, 757 F.2d 1344 (1st Cir. 1985) (upholding the denial of class certification to a class seeing injunctive relief "on [the] ground that [any] injunctive or declaratory relief would inure to [the] benefit of all those similarly situated").

[40] *See, e.g. Simpson v. Heckler*, 630 F.Supp. 736 (E.D. Pa. 1986) (class certification denied because all prerequisites of Rule 23(a) were not met and any injunctive and declaratory relief awarded would have the effect of a class action). *See also Katz v. Carte Blanche Corp.*, 496 F.2d 747, 757 (3d Cir. 1974) (court may consider: "(1) an informed consideration of alternative available methods of adjudication of each issue, (2) a comparison of the fairness to all whose interests may be involved between such alternative methods and a class action, and (3) a comparison of efficiency of adjudication of each method").

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 13, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on May 13, 2008 upon the following parties:

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